THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today

- (1) was not written for publication in a law journal and
- (2) is not binding precedent of the Board.

Paper No. 44

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS

AND INTERFERENCES

Ex parte EDWARD L. SINOFSKY

Appeal No. 95-0065 Application 07/568,348¹

ON BRIEF

Before CALVERT, COHEN and CRAWFORD, <u>Administrative Patent</u> <u>Judges</u>.

CALVERT, Administrative Patent Judge.

¹ Application for patent filed August 15, 1990. According to appellant, the application is a continuation of Application 07/257,760, filed October 14, 1988, now U.S. Patent 4,950,266, issued August 21, 1990; which is a continuation of Application 07/014,990, filed February 17, 1987, abandoned; which is a continuation of Application 06/761,188, filed July 31, 1985, abandoned.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 44 to 70. Claims 71 to 76, the other claims remaining in the application, stand withdrawn from consideration under 37 CFR § 1.142(b) as being directed to a nonelected invention.

The claims on appeal are drawn to a system and method for the removal of biological tissue within a body, and a copy thereof is included in Appendix A of appellants' brief.²

The references applied in the final rejection are:

L'Esperance 1976	3,982,541	Sept.	28,
Esterowitz et al. (Esterowitz) 1982	4,321,559	Mar.	23,
Madone et al. (Madone) 1984	4,445,918	May	1,
Takano 1984³	4,454,882	June	19,
Sinofsky 1990	4,950,266	Aug.	21,

² References in this decision to appellant's brief are to the brief filed on November 29, 1993; to the examiner's answer are to the answer mailed on February 2, 1995; and to appellant's reply brief are to the reply brief filed on February 25, 1998.

 $^{\,^{\}scriptscriptstyle 3}$ We note that this reference was not listed on page 2 of the examiner's answer.

Wolbarsht, <u>Interactions between material processing and surgery</u>, ICALEO, 4/L.I.A., vol. 32 (1982)

Horn et al. (Horn), <u>A new "cool" lens capsulotomy laser</u>, Am. Intra-Ocular Implant Soc. J., vol. 8, pp. 337-342 (Fall 1982)

The claims on appeal are rejected as follows:

- (1) Claims 44 to 70 stand rejected under 35 U.S.C. § 103 as unpatentable over the following combinations of references:
- (a) Claims 44, 49, 52 to 54, 57, 62, 64 to 68 and 70, over Wolbarsht in view of Horn and L'Esperance;
- (b) Claims 46 to 48, 50, 56, 59 to 61 and 63, over Wolbarsht in view of Horn, L'Esperance and Esterowitz;
- (c) Claims 45, 55, 58^4 and 69, over Wolbarsht in view of Horn, L'Esperance and Madone;
- (d) Claim 51, over Wolbarsht in view of Horn, L'Esperance and Takano.

⁴ On page 5, line 11, and page 8, line 4, of the answer, this claim is incorrectly identified as "48."

(2) Claim 54 stands rejected under 35 U.S.C. § 101 as unpatentable over claim 15 of Sinofsky on the ground of double patenting.

Rejection (1)(a)

The examiner states the basis of this rejection on page 4 of the answer as:

Wolbarsht (1982) teaches using wavelengths which are highly absorbed by the tissue to be removed and suggest[s] that wavelengths absorbed by water are desirable. Horn et al

teach the desirability of avoiding damage to intervening tissues when applying laser radiation and discuss the use of an Er: YLF laser and a pulse width of 10 nanoseconds.

L'Esperance teaches the desirability of employing an optical fiber to apply laser

radiation. It would have been obvious to the artisan of ordinary skill to employ an optical fiber in the device of Wolbarsht (1982), since this provides more flexibility of manipulation, as taught by L'Esperance (see column 3, line 65 - column 4, line 5) and to employ a wavelength in the range of 1.4-2.2 micrometers, since these are strongly absorbed by water, as shown by Horn et al (see the first paragraph under DISCUSSION) and Wolbarsht (see figure 1 and the last paragraph on the second page of Wolbarsht); and to employ

pulse widths and energy densities capable of vaporizing tissue such as those claimed since these are not critical; are well within the scope of one of ordinary skill in the art; and are necessary to remove the tissue, thus producing a device such as claimed.

The Wolbarsht article is concerned with the use of lasers in surgery in general, although surgery inside the eye and plastic surgery are mentioned in the last paragraph on the fourth page. The article is concerned primarily with the CO₂ laser. However, in the last paragraph on the second page, referred to by the examiner, supra, Wolbarsht states:

To assist in confining the thermal effects to the surface layer, the laser wavelength must be matched as closely as possible to the absorption peak of the material in question. The absorption spectrum of water, as given in Figure 1, shows a peak near 2.8 μm , although the absorption is certainly sufficiently high at 10.6 μm to be adequate to make the CO₂ laser work for tissue cutting. However, for the maximum absorption in the shortest tissue

distance, a laser in the range from 2.7 to $3.1~\mu m$ would seem to offer some advantage.

The accompanying Figure 1, like appellant's Fig. 1, plots the absorption in water versus various wavelengths. Two peaks appear to be shown in the wavelength range claimed by appellant: one at about 1.4 μm , the other at about 1.9 μm . Both peaks are less than the absorption shown for a CO₂ laser (10.6 μm), and considerably less than the maximum absorption shown at the peak disclosed by Wolbarsht as being "near 2.8 μm ."

The Horn article concerns the use of a laser for use in ophthalmology, specifically, for capsulotomy. Horn discloses that a wavelength better suited for lens capsulotomy is an infrared laser operating in the 1200-1300 nm (1.2 to 1.3 µm) wavelength region. The laser may be a frequency-doubled neodymium-YAG laser; also (page 338, second column):

A second generation laser, the erbium yttrium lithium fluoride (erbium-YLF) laser, has recently been developed. It produces short pulses at a wavelength of 1228 nm, and is lightweight and compact.

⁵ <u>Stedman's Medical Dictionary</u> (24th Ed., 1982) defines "capsulotomy" as "[i]ncision through a capsule, specifically, the capsule of the lens in the extracapsular cataract operation."

In the first paragraph under "DISCUSSION" on page 340, to which the examiner refers, supra, Horn discloses the desirable characteristics of a laser used for lens capsulotomies, as follows:

The new "cool" lens capsulotomy laser described in this report was developed to operate at a previously untried wavelength region: 1200-1290 nm. This region is well suited for lens capsulotomies, having high corneal and anterior segment transmission, high intraocular lens transmission, low ocular media transmission and retinal absorption, and relatively high water absorption.

L'Esperance discloses apparatus for performing surgery on the eye, using a CO_2 laser. In a variation shown in Fig. 4, L'Esperance discloses that the laser beam may be transmitted to the probe at the distal end through a fiber optics bundle 62. However, in that case L'Esperance states that "[w]hen using bundle 62 the laser 22 should be some type other than carbon dioxide such as argon" (col. 4, lines 2 to 4).

We have carefully considered the record in light of the arguments presented in appellant's brief and reply brief, and in the examiner's answer. We conclude that, although the references

applied by the examiner are certainly relevant to the use of a laser to remove biological tissue, they do not make out a case of prima facie obviousness with regard to the subject matter claimed by appellant.

Although wavelengths in the claimed range of 1.4 to 2.2 μ m are shown by Wolbarsht's Fig. 1 as having some absorption in water, their absorption is not shown as being as high as either the CO₂ laser (10.6 μ m) discussed by Wolbarsht or the 2.7 to 3.1 μ m range disclosed by him as having maximum absorption and therefore "seem[ing] to offer some advantage." In view of Wolbarsht's teaching of using lasers with high absorption in water, we do not consider that one of ordinary skill would find therein any suggestion or motivation to use lasers, such as lasers in the claimed 1.4 to 2.2 μ m range, whose wavelengths are disclosed as not having as high an

absorption as the wavelengths of the CO_2 laser or of lasers in the 2.7 to 3.1 μm range.

The Horn article, as the examiner points out, does disclose the use of an erbium-YLF laser, which is one of the lasers disclosed by appellant as useable in his invention.

However, Horn's only reference to this laser is on page 338 (quoted supra), and there he stated that it produces short pulses

at a wavelength of 1.228 $\mu m\,,$ which is outside of appellant's claimed range.

In the paragraph on page 340 which is quoted above, Horn discloses certain criteria for a lens capsulotomy laser, including, inter alia, high corneal transmission, low ocular media transmission, and low retinal absorption. Figs 3b and 3c on the same page show that a wavelength of 1.4 or 1.5 μ m would meet the latter two criteria. On the other hand, however, Fig. 3a shows that at Horn's recommended wavelengths of 1.20 to 1.29 μ m (1200 to 1290 nm), the corneal transmission is in the 90% region, while at wavelengths of 1.4 to 2.2 μ m corneal transmission is lower, with a peak of

about 70% at around 1.6 μ m, falling to zero at 1.9 μ m. Here again, as with the Wolbarsht reference, it is not apparent to us what suggestion there would be in Horn for one of ordinary skill in the art to ignore Horn's teaching that the corneal transmission should be high and use wavelengths of 1.4 to 2.2 μ m, none of which, as shown in Horn's Fig. 3a, has a corneal transmittance as high as the transmittance for the 1.20 to 1.29 μ m range recommended by Horn.

On page 15 of the answer, the examiner argues that appellant has simply discovered an optimum value for a known process, citing In re Aller, 220 F.2d 454, 105 USPQ 233 (CCPA 1955). We do not consider this argument to be well taken, for in the present case appellant did not discover the optimum wavelength from a broad range of wavelengths taught by the prior art, but rather used wavelengths which are outside the ranges

suggested by Wolbarsht or Horn, and in fact, as discussed above, might be considered to be contrary to the suggestions of the references. Thus, unlike <u>Aller</u>, appellant did not

simply discover the optimum or working ranges from general conditions disclosed in the prior art.

In our view, one of ordinary skill in the art considering Wolbarsht, Horn and L'Esperance would at most derive therefrom a suggestion to use wavelengths in the 1.2 to 1.3 µm range (as disclosed by Horn) rather than the 2.7 to 3.1 µm or 10.6 µm wavelengths disclosed by Wolbarsht, and we find no suggestion in the combination of these three references to use wavelengths in appellant's claimed 1.4 to 2.2 µm range. Rejection (1)(a) will therefore not be sustained.

Rejections (1)(b)(c) and (d)

These rejections likewise will not be sustained, since the additional references applied therein do not overcome the above-discussed deficiencies in the basic combination of Wolbarsht, Horn and L'Esperance.

Rejection (2)

The examiner takes the position that claim 54 is unpatentable under 35 U.S.C. § 101 over claim 15 of Sinofsky

(appellant's prior patent) on the ground of "same invention" type double patenting.

Claim 54 reads (underlining added):

54. A system for the removal of <u>biological tissue</u> within a body comprising:

a laser energy source including means for operating said laser energy source in a pulsed mode with an output wavelength in a range of 1.4 - 2.2 micrometers and for operating said laser energy source at an energy level of at least about one joule per pulse for a surgical site of the order of 1.5 millimeters in diameter to remove biological tissue within the body;

an optical fiber for conducting laser energy from said laser energy source from a proximal end of said fiber to a surgical site at a distal end of said optical fiber; and

means for directing an output of said laser source to the proximal end of said optical fiber.

Claim 15 differs from claim 54 only in that (1) instead of the first underlined portion, claim 15 recites "artherosclerotic plaque"; and (2) claim 15 omits the second underlined portion.

⁶ Since the disclosures of the patent and the instant application are the same, there is no difference between claim 54 and claim 15 as to the coverage of the recited means-plusfunction elements.

Appellant, on page 44 of the brief, cites the test for "same invention" double patenting set forth in <u>In re</u>

<u>Vogel</u>, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970), i.e.:

A good test, and probably the only objective test, for "same invention," is whether one of the claims could be literally infringed without literally infringing the other. If it could be, the claims do not define identically the same invention.

See also In re Hallman, 655 F.2d 212, 216, 210 USPQ 609, 611-12 (CCPA 1981). Appellant contends that there is no "same invention" double patenting here, because claim 15 would not be infringed if the invention claimed in claim 54 were used to remove bodily tissue other than artherosclerotic plaque.

We do not agree. The claimed subject matter here is a system, not a method of use. The recitation of a new use for an old product does not make a claim to that product patentable. In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997); La Bounty Mfg. Inc. v. ITC, 958 F.2d 1066, 1075, 22 USPQ2d 1025, 1032 (Fed. Cir. 1992).

could not construct a <u>system</u> or <u>structure</u> on which claim 54 would read but claim 15 would not read, and vice versa. <u>Cf.</u>

<u>In re Knohl</u>, 386 F.2d 476, 480, 155 USPQ 586, 590 (CCPA 1967).

Appellant argues (brief, page 46)

that the recitation "to remove biological tissue within the body" is more than a statement of intended use because it "defines the character of the radiation being emitted by the

source," but, as the examiner indicates on page 28 of the answer,

appellant does not state "in what way this would provide some sort of distinguishing structural relation."

Rejection (2) will accordingly be sustained.

Conclusion

laser energy

The examiner's decision to reject claims 44 to 70 under 35 U.S.C. § 103 is reversed, and to reject claim 54 under 35 U.S.C. § 101 is affirmed.

No time period for taking any subsequent action in con- nection with this appeal may be extended under 37 CFR § 1.136(a).

<u>AFFIRMED-IN-PART</u>

	IAN A. CALVERT Administrative Patent	Judge)))		
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